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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,114	12/05/2003	Scott A. Burton	59098US002	3162

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
08/12/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com
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Office Action Summary	Application No.	Applicant(s)	
	10/729,114	BURTON ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/02/2009; 04/09/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and IDS, both filed 04/09/2009; and IDS filed 03/02/2009.

Claim4 has been canceled.

Claims 1-3, and 5-28 are pending and included in the prosecution.

The following rejection has been overcome by virtue of applicants' amendment and remarks:

The rejection of claims 26 and 28 under 35 U.S.C. 112 first paragraph, as failing to comply with the written description requirement.

The following rejections have been discussed in details in the previous office action, and are maintained for reasons of record:

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-3, 5-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-73 of copending Application No. 10/728,577. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: wound dressing comprising organic polymeric matrix and hydrophilic microparticles. The difference between the present claims and the conflicting claims is that the present claims recite substrate. The substrate is known in the art of wound dressing, and one having ordinary skill in the art would have provided substrate to support the polymer matrix. The present claims and the conflicting claims of the copending application are obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. The examiner acknowledged applicant's intention to provide an appropriate response to the double patenting rejection upon an indication of otherwise allowable subject matter and in the event this rejection is maintained. However, "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-3, 5-8, 13-18, 21, and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/066087 ('087).

The present claim 1 is directed to composition comprising hydrophobic organic polymer matrix, hydrophilic organic microparticles having particle size of 10 microns or less, and optionally plasticizer.

WO '087 teaches medical article comprising a composition comprising a polymeric matrix and absorbent particles of microcolloid having particle sizes less than 10 microns (abstract; page 3, 7th paragraph; page 7, 1st paragraph; page 11, 3rd paragraph; page 12; page 28, claims 3 and 4), and preferably the particle size less than 1 micron (page 4). The microcolloid particles form from 5-100% by weight of the composition (page 5, 3rd paragraph). The composition further comprises a plasticizer (page 14, 3rd paragraph; page 18, 2nd paragraph). The particles are dry powder, i.e. nonhydrated (page 5, last paragraph). The microcolloid particles of the composition delivered in a carrier liquid in the form of a suspension, as required by claim 13, and also on claims 26 and 28 that require liquid (page 6, 1st paragraph; page 12, 9th paragraph). The particles are made of acrylic acid polymer (page 15, 1st paragraph; page 16, 4th paragraph). The polymeric matrix is preferably hydrophobic (page 6, 6th paragraph). The polymer matrix comprises S-EB-S as claimed by claim 25 (polystyrene-

polyethylene/butylene-polystyrene), S-I-S and S-B-S copolymers (page 17, 5th paragraph). The polymer matrix may contain combination of polymers (page 17, 3rd paragraph; page 18, 3rd paragraph). The composition is coated on porous substrate to form wound dressing that absorbs wound exudates (page 9, 2nd and 3rd paragraphs). The matrix further comprises active agents including antibacterial agents (page 19, 3rd paragraph).

Although WO '087 teaches polymer matrix having the same ingredients as instantly claimed, however, the reference does not explicitly teach that the composition displays the peel strength from stainless steel as instantly claimed by claims 1, 19 and 20. However, those of ordinary skill in the art would have been readily optimized effective amount of each ingredient as determined by desired properties and intended use of the composition and site of application of the wound dressing. Determination of the appropriate amounts involving each of the above mentioned ingredients would have been routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of the dosage information disclosed prior art.

While WO '087 teaches fine pore sizes of the porous substrate, it does not explicitly teach pore size of 1 mm to 0.5 cm as claimed by claim 8 or the number of the pores per square cm as claimed by claim 7. It is the examiner's position that the pore size and their number are result effective variables because changing them will clearly affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that "discovery of an optimum value of a result effective variable in a known process is

ordinarily within the skill of the art." See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Evidence to support the examiner's position is found in WO '087 in page 10, 1st paragraph, where the reference teaches that porosity can be controlled and higher porosity is advantageous.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to adjust the amount of different ingredients of the composition disclosed by WO '087 to achieve the desired degree of adhesiveness of the composition, and to utilize appropriate pore sizes and numbers of pores of the substrate/square unite, including those within the scope of the present claims, so as to produce desired end results of moisture absorption and thereby arrive at the presently cited claims.

7. Claims 9-11, 19, 20, 22, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '087 in view of the article "SALCARE® SC95" by Ciba®.

The teachings of WO '087 are previously discussed as set forth in this office action.

Although WO '087 teaches varieties of materials of the microcolloidal particles including acrylic polymers, however, the reference does not specifically teach the specific material of the microparticles as claimed by claims 9-11, 19, 20, 22, and 23.

The article teaches that "SALCARE® SC95" is a cationic homopolymer dispersed in medicinal grade white oil. SALCARE® SC95 does not require pre-mixing or special

equipment, has high thickening efficiency, and gives good uniform performance when incorporated in cosmetics.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide medical article comprising a polymer composition comprising a hydrophobic polymeric matrix and absorbent particles of acrylic acid polymers as disclosed by WO '087, and replace the acrylic acid particles by SALCARE® SC95 particles disclosed by the article of Ciba®. One would have been motivated to do so because of the article of Ciba® teaches that such material does not require pre-mixing or special equipment, has high thickening efficiency, and gives good uniform performance when incorporated in cosmetics. One would have reasonably expected formulating medical article comprising a polymer composition comprising a hydrophobic polymeric matrix and absorbent particles made of SALCARE® SC95 that is safe to the skin and easy to produce.

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO '087 in view of US 4,902,565 ('565).

The teachings of WO '087 are previously discussed as set forth in this office action.

Although WO '087 teaches varieties of materials of the microcolloidal particles including acrylic polymers, however, the reference does not specifically teach the specific material of the microparticles as claimed by claim 12.

US '565 teaches wound dressings having porous substrate that is preferably a foamed plastics material having interconnecting cells and advantageously having a fine pore size to provide greatest surface area and fastest water uptake (col.3, lines 6-15). The substrate comprises solid water absorbing particles that are preferably finely powdered, having high water absorbing and retaining properties. Examples of suitable polymer materials are polymers or copolymers of acrylamide or polymers of one or more acrylic monomers with acrylic or methacrylic acid. When unsaturated acid monomers are employed, the acid groups may be neutralized by treatment with an alkali metal hydroxide, such as sodium hydroxide, which reads on the copolymer of claim 12. Preferably, the particulate, water-absorbing material has a particle size of less than 50 microns (col.2, lines 1-21).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide medical article comprising a polymer composition comprising a hydrophobic polymeric matrix and absorbent particles of acrylic acid polymers as disclosed by WO '087, and replace the acrylic acid particles by particles comprising copolymer of acrylate salt and acrylic acid as disclosed by US '565. One would have been motivated to do so because US '565 teaches that such particles have high water absorbing and retaining properties. One would reasonably expected formulating medical article comprising a polymer composition comprising a hydrophobic polymeric matrix and absorbent particles of copolymer of acrylate salt and acrylic acid that has high water absorption capacity and retaining properties that are advantageous to the wound dressing and wound healing.

Response to Arguments

9. Applicant's arguments filed 04/09/2009 have been fully considered but they are not persuasive.

Applicants argue that WO '087 is not directed to non-adherent composition, but adhesive. Starting with an adhesive composition and modifying it to be nonadhesive is not a routine matter. Adhesive compositions are complex compositions and are not necessarily simply made nonadhesive by taking something out. In the present case, the "adhesive" is a property of the composition of the reference and not a component of the composition. The adhesive property results from the types and amounts of components, not from "adhesive component." In reality, one of skill in the art looking for a nonadhesive composition does not necessarily start with an adhesive composition and modify it to be nonadhesive. Further, applicants argue that if one were looking at WO 087 to determine how one would remove the "adhesive property" of the adhesive composition described therein, one would be led to use different particles than are claimed by Applicants. WO '087 provides data that demonstrates its compositions have reduced adhesion if particles having larger particle size are incorporated therein, Tables 2 and 5 of WO '087. Reduced adhesion occurs with AQUASORB A500, which is used in Adhesive A2 (hydrocolloid Control) that has a particle size range of 75 to 250 microns, as opposed to the microcolloid used in Adhesive A1, which has a particle size range of 0.5 to 1 micron.

In response to this argument, it is argued that the present claim is directed to a product, and all the elements of the product are taught by the WO '087. In page17 of the reference, 2nd and 3rd paragraphs, the reference teaches that adhesiveness strength of the composition is determined by selecting the type of the adhesive phase of the composition. The present claims recite the same adhesives, and adhesives are not excluded from the present claims. Therefore, WO '087 suggested variation of the adhesive strength by manipulating the type of adhesive polymer used. The claimed ingredients of the polymer composition are taught by the prior art in the same concentrations including adhesives such as S-EB-S, S-I-S and S-B-S copolymers. Therefore, the polymer composition of the reference is expected to have the same properties since materials and their properties are inseparable. It is further noticed that the adherence of the product is measured by the peel strength of the whole product, and applicant did not show the peel strength of the polymer composition by itself. In page 3 of the present specification, lines 27-30, applicant stated that: "In the context of the polymer composition, **the term "nonadherent" means that a composition of the present invention coated on a substrate** displays a 180° peel strength of less than 1 Newton per centimeter (N/cm) from stainless steel according the to test procedure described in the Examples Section." The claimed peel strength disclosed by the reference is that of the polymer composition only while the claimed higher peel strength, which means less adhesiveness, is that of the whole product comprising the polymer composition and the apertured substrate. In other words, when the composition of the prior art is placed on apertured substrate it is expected that the composition will

permeate through the pores of the substrate and become less adherent. The composition of the prior art is used for the same purpose as wound dressing as the present claims. The burden is on applicants to show that the polymer composition disposed on the porous substrate disclosed by the prior art is adhesive and that the present product resulted in novel and unobvious difference between the claimed product and prior art product since the Patent Office does not have the facilities for preparing the claimed materials and comparing them with the prior art inventions. See *In re Best*, 562 F.2 1252, 195 USPQ 430 (CCPA 1977); and *In re Fitzgerald et al.*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require

absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-

0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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